

Global AlcHep Invitation Letter

February 22th, 2023

Dear Researcher,

We would like to invite you to join **Global AlcHep**, a *big data* network that aims to develop a large multinational de-identified clinical database in alcohol-associated liver disease (ALD). We are initially focusing on alcohol-associated hepatitis (AH). Our goal is to create a centralized database registry that captures patients' main demographic and clinical characteristics with AH at a global level, enabling large-scale studies to identify the main trends and determinants of clinical outcomes.

So far, we have performed two large retrospective studies that shared multiple participating centers and we have successfully generated four publications. Besides the existing **RETRO** database, we are asking all Global AlcHep members (both previous and new collaborators) if they would be interested in a prospective database (**PRO-STUDY**). We are working on a RedCap database that will be reviewed by all participating centers. Our idea is to launch a platform for new collaborative studies. We will have 3 types of studies: 1. Retrospective studies with the existing data; 2. Retrospective studies which require some extra data collection; and 3. Prospective studies.

We are very excited about this initiative, which has gathered over 80 centers from different continents. Our group is quite diverse in geography and experience, which will serve us well. I appreciate the support of all of you in this project. For fairness, future authorship order will depend on participation/analysis and number of completed patients' case report forms (CRFs).

Some additional details on the project:

- <u>Budget</u>: This project does not count with a specific budget at this point for the participating centers. Each center will use its own resources to collect the information.
- <u>Statement of financing</u>: research coordinators and statisticians at both leading centers (Western University, Canada; and Hospital Clinic Barcelona, Spain) will be financed by Global AlcHep Principal Investigators to support data management, security, and analysis.
- <u>Declaration of infrastructure of the participating center</u>: Both leading centers declare that we have the necessary infrastructure to support this research project. Our infrastructure includes the following:
 - Hardware: Our center possesses adequate computing hardware such as desktops, laptops, and servers to handle the data processing, storage, and analysis required for this study.
 - Software: We have the necessary software tools and licenses to support the data management, analysis, and visualization required for this research project.
 - Network: Our center has a robust network infrastructure with adequate bandwidth to support data transfer and communication with the study team and other participating centers.
 - Security: We have established security protocols and procedures to ensure that the data we handle is protected against unauthorized access, theft, or loss.
 - o Data Management: We have qualified personnel with expertise in data management who will ensure that the data is collected, stored, and managed in a secure and compliant manner.

- Ethics and regulatory compliance: We are committed to adhering to the highest ethical standards and will comply with all applicable laws, regulations, and guidelines governing data protection and privacy.
- Quality Control: We have established quality control measures to ensure that the data collected is accurate, complete, and reliable.
- o Human Resources: We have adequate personnel with the necessary expertise, experience, and qualifications to perform the tasks assigned to our center in this study.
- Training: We have provided adequate training to our personnel on the study protocols, data management procedures, and ethical considerations.
- We hereby declare that we are committed to upholding the highest standards of quality, compliance, and ethical conduct throughout the study.

We would really appreciate it if you could join us to advance in this disease together!

Sincerely yours,

Juan Pablo Arab, MD

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